

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ASTELLAS INSTITUTE FOR
REGENERATIVE MEDICINE, et al.,

Plaintiffs,

v.

IMSTEM BIOTECHNOLOGY, INC., et al.,

Defendants.

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Civil Action No. 17-cv-12239-ADB

**MEMORANDUM AND ORDER ON DEFENDANTS' MOTION TO AMEND
COUNTERCLAIMS**

BURROUGHS, D.J.

Plaintiffs Astellas Institute for Regenerative Medicine (“Astellas”) and Stem Cell & Regenerative Medicine International, Inc. (“SCRMI”) (collectively, “Plaintiffs”) filed this action against Defendants ImStem Biotechnology, Inc. (“ImStem”), Dr. Xiaofang Wang (“Dr. Wang”), and Dr. Ren-He Xu (“Dr. Xu”) (collectively, “Defendants”) alleging claims for correction of inventorship under 35 U.S.C. § 256, unfair trade practices under Massachusetts General Laws Chapter 93A, conversion, unjust enrichment, misappropriation of trade secrets, and negligent misrepresentation. [ECF No. 1]. ImStem and Dr. Wang brought counterclaims against Plaintiffs for correction of inventorship under 35 U.S.C. § 256 and unjust enrichment (“Counterclaim Complaint”). [ECF No. 20]. Currently pending before the Court is Defendants’ motion to amend the Counterclaim Complaint.¹ [ECF No. 70]. For the following reasons, Defendants’ motion to amend [ECF No. 70] is GRANTED in part and DENIED in part.

¹ The Counterclaim Complaint was filed on behalf of ImStem and Dr. Wang, but the motion to amend the Counterclaim Complaint is brought by all Defendants. See [ECF Nos. 20, 70, 71-2].

I. BACKGROUND

The Court presumes familiarity with the facts of this case and therefore briefly recounts the procedural history of this case and describes the patents-in-suit. On February 24, 2015, the U.S. Patent and Trademark Office (“PTO”) issued U.S. Patent Nos. 8,961,956 (the “’956 Patent”) and 8,962,321 (the “’321 Patent”), which are both entitled “Mesenchymal Stromal Cells and Uses Related Thereto,” and name, *inter alia*, Drs. Erin Kimbrel and Robert Lanza as joint inventors. [ECF Nos. 20-1, 71-2]. Neither patent names Drs. Wang or Xu as a joint inventor. On August 29, 2017, the PTO issued U.S. Patent No. 9,745,551 (the “’551 Patent”), entitled “Mesenchymal-Like Stem Cells Derived from Human Embryonic Stem Cells, Methods and Uses Thereof,” which names Drs. Wang and Xu as joint inventors. [ECF No. 1-1]. The ’551 Patent does not name Drs. Kimbrel and Lanza as joint inventors.

On November 13, 2017, Plaintiffs filed suit against Defendants, seeking a correction of inventorship on the ’551 Patent and other state law remedies. [ECF No. 1]. On January 10, 2018, ImStem and Dr. Wang filed an answer and the Counterclaim Complaint. [ECF No. 20]. On January 31, 2018, Plaintiffs moved to dismiss the Counterclaim Complaint, which the Court denied on September 28, 2018. [ECF Nos. 21, 37]. On June 8, 2018, Dr. Xu filed an answer. [ECF No. 33].

On October 16, 2018, the Court issued a schedule pursuant to Federal Rule of Civil Procedure 16(b) that required all motions to amend pleadings to be served by October 29, 2018 and set March 8, 2019 as the date for the close of fact discovery. [ECF No. 44]. Fact discovery was extended multiple times and was finally scheduled to close on July 19, 2019. See [ECF Nos. 51, 57, 68]. Late in the evening on July 22, 2019, Defendants filed the instant motion to amend. [ECF No. 70]. On July 23, 2019, the Court held a status conference at which it permitted

Plaintiffs to respond to the proposed amendment and instructed the parties to submit a proposed schedule extending discovery once again were the motion to be allowed. [ECF No. 72 (“Parties will propose [a] new schedule that will have the case trial ready for April.”)]. On July 30, 2019, Plaintiffs opposed the motion to amend. [ECF No. 75]. On August 5, 2019, with leave of the Court, Defendants filed a reply brief. [ECF No. 81].

II. DISCUSSION

Under Federal Rule of Civil Procedure 15(a), where a party seeks to amend a pleading more than 21 days after a motion to dismiss or answer has been filed, it may only do so “with the opposing party’s written consent or the court’s leave.” Fed. R. Civ. P. 15(a)(2). Rule 15 instructs that leave to amend should be “freely give[n] . . . when justice so requires.” *Id.* “At a certain point,” however, “this amendment-friendly regime may cease to govern.” *U.S. ex rel. D’Agostino v. EV3, Inc.*, 802 F.3d 188, 192 (1st Cir. 2015). In cases where a district court has issued a scheduling order under Rule 16(b) and the amendment sought contravenes a deadline imposed by the court, “Rule 16(b)’s more stringent good cause standard supplants Rule 15(a)’s leave freely given standard.” *Id.* (first citing *Cruz v. Bristol-Myers Squibb Co., P.R.*, 699 F.3d 563, 569 (1st Cir. 2012) and then citing *Trans-Spec Truck Serv., Inc. v. Caterpillar Inc.*, 524 F.3d 315, 327 (1st Cir. 2008)). “Rule 16(b)’s ‘good cause’ standard emphasizes the diligence of the party seeking the amendment.” *O’Connell v. Hyatt Hotels*, 357 F.3d 152, 154–55 (1st Cir. 2004). Under this inquiry, “[p]rejudice to the opposing party remains relevant but is not the dominant criterion.” *Id.* Rather, “[i]ndifference’ by the moving party” may preclude leave to amend “irrespective of prejudice because such conduct is incompatible with the showing of diligence necessary to establish good cause.” *Id.*

Here, Defendants propose the following amendments: (i) add the affirmative defense of statute of limitations, (ii) add a correction of inventorship counterclaim on behalf of Drs. Wang and Xu concerning the '321 Patent, and (iii) add Dr. Xu to the existing correction of inventorship counterclaim concerning the '956 Patent. See [ECF No. 71-2]. As Defendants' request for leave to amend the pleadings is not timely, the Court reviews Defendants' request under Rule 16(b)'s "good cause" standard.

1. Statute of Limitations Defense

Defendants seek to amend their answer to add a statute of limitations defense. See [ECF No. 71-2 at 13].² After hearing the parties on July 23, 2019 and reviewing the briefing submitted, the Court concludes that there is good cause to permit the amendment and that there was no waiver. First, Defendants have shown that there is good cause for the amendment by demonstrating to the Court that they were reasonably diligent in learning of the affirmative defense and presenting it to the Court. See [ECF No. 81 at 6–8]. Even if they learned of the defense as early as January 2019 when Plaintiffs began producing documents, which is unlikely, presenting the amendment less than six months later before discovery has closed and summary judgment briefing has begun does not establish undue delay. All but one of the cases on which Plaintiffs rely in opposing the amendment are inapposite because they involve situations in which a statute of limitations defense was raised on the eve of, or during, trial. See In re Cumberland Farms, Inc., 284 F.3d 216, 225 (1st Cir. 2002) (affirmative defense raised on "the eve of trial"); Knapp Shoes, Inc. v. Sylvania Shoe Mfg. Corp., 15 F.3d 1222, 1226 (1st Cir.

² Defendants did not brief the request to add an affirmative defense; instead, the additional defense was included in the proposed amended pleading submitted with the motion to amend. [ECF No. 71-2 at 13]. The request was raised orally at the July 23, 2019 hearing, during which the Court advised Defendants that it was unnecessary to file an amended or supplemental motion addressing the defense.

1994) (affirmative defense raised on “the ninth and final day of the liability phase of trial”); Jakobsen v. Mass. Port Auth., 520 F.2d 810, 813 (1st Cir. 1975) (affirmative defense raised “for the first time in a motion for a directed verdict”). In the remaining case, Perlmutter v. Shatzer, 102 F.R.D. 245 (D. Mass. 1984), the defendant sought to add a statute of limitations defense five years into the case, which was initially allowed by the Court as unopposed and then was denied on reconsideration. 102 F.R.D. at 246–49. The court in Perlmutter concluded that defendant had unduly delayed in raising the defense because it “had notice since the outset of the litigation that the defense was available” and that “defendant’s undue delay . . . has significantly prejudiced the plaintiff . . .” Id. at 248–49. The same cannot be said here.

Plaintiffs argue that they will be prejudiced by the amendment, but muster only that they were unable “to gather discovery on this defense and consider the impact of such a defense.” [ECF No. 79 at 24]. To the extent that Plaintiffs will require additional discovery concerning a statute of limitations defense, the Court’s approval of an extension to fact discovery addresses their concern. See Gouin v. Nolan Assocs., LLC, 325 F.R.D. 521, 523 (D. Mass. 2017) (concluding that amendment would not prejudice non-moving party where court also permitted motion to extend discovery deadlines and trial date).

Second, Defendants did not waive a statute of limitations defense by omitting it from their original pleadings because they were not aware of the information establishing the viability of the defense at that time. See [ECF Nos. 20, 33]; cf. Davignon v. Clemmey, 322 F.3d 1, 15 (1st Cir. 2003). As a general rule, affirmative defenses, including statute of limitations, should be raised in the responsive pleading. Fed. R. Civ. P. 8(c). The purpose of Federal Rule of Civil Procedure 8(c) is “to give the parties, and the court, ‘fair warning that a particular line of defense will be pursued,’” Keefe v. Locals 805, Int’l Longshoremen’s Ass’n, AFL-CIO, No. 04-cv-

11340-DPW, 2007 WL 2461045, at *6 (D. Mass. Aug. 23, 2007) (quoting Williams v. Ashland Eng'g Co., 45 F.3d 588, 593 (1st Cir. 1995)), and to “afford[] an opportunity to develop any evidence and offer responsive arguments relating to the defense,” Davignon, 322 F.3d at 15. The First Circuit has held that a party’s failure to plead an affirmative defense generally results in waiver of the defense and its exclusion from the case. See Jewelers Mut. Ins. v. N. Barquet, Inc., 410 F.3d 2, 11 (1st Cir. 2005); Knapp Shoes, 15 F.3d at 1226.

There are limited exceptions to a Rule 8(c) waiver, however, including “where (i) the defendant asserts [the affirmative defense] without undue delay and the plaintiff is not unfairly prejudiced by any delay, or (ii) the circumstances necessary to establish entitlement to the affirmative defense did not obtain at the time the answer was filed.” Davignon, 322 F.3d at 15. In the latter situation, the First Circuit has made clear that the appropriate course of action is to seek leave to amend the answer. Depositors Trust Co., 692 F.2d at 208 (stating that “[a] party may also have recourse to a late discovered affirmative defense by obtaining leave to amend his [pleading]”). “[C]ases which permit the interposition of an affirmative defense outside the pleadings generally have involved moderate delays, such as an attempt to raise the defense in a pretrial motion to dismiss or for summary judgment, rather than at trial or in a postjudgment motion.” Davignon, 322 F.3d at 16; see Rockingham Cty. Nursing Home v. Harnois, No. 11-cv-11057-JGD, 2014 WL 176580, at *1–2 (D. Mass. Jan. 10, 2014) (permitting amendment to add statute of limitations defense that was requested following the conclusion of briefing on summary judgment, but before trial).

This case is an example of a moderate delay due to learning of the availability of the defense after the deadlines for answering or amending have lapsed. Defendants were not in possession of the relevant materials as of January 10, 2018 or June 8, 2018, the dates the answers

were filed, or even as of October 28, 2018, the deadline for amendment, because Plaintiffs did not produce documents until January 2019. See [ECF No. 71 at 7–8]. Having learned of information supporting a statute of limitations defense following the relevant deadlines, Defendants took the recommended course of conduct and sought to amend their pleading. See Depositors Trust Co., 692 F.2d at 208. Although the Court does not countenance Defendants’ counsel’s somewhat surreptitious approach to requesting the amendment, the Court will allow the amendment for the reasons described above.

2. The Correction of Inventorship Claim for the ’321 Patent

Defendants also propose to add a correction of inventorship claim for the ’321 Patent pursuant to 35 U.S.C. § 256. [ECF No. 71-2 ¶¶ 42–48]. The amended Counterclaim Complaint alleges that “[t]he idea of mitotically inactivating HB-MSCs in preparation for clinical use is a highly valuable aspect of the invention that gave rise to the ’321 Patent,” “[t]he idea of . . . comparing HB-MSCs to bone-marrow-derived MSCs and determining greater potency is a valuable aspect of the invention that gave rise to the ’321 Patent,” and that Drs. Wang and Xu contributed to those ideas. [Id. ¶ 43]. It further alleges that Drs. Kimbrel and Lanza claimed Drs. Wang and Xu’s ideas as their own in the provisional patent application that became the ’321 Patent and omitted Drs. Wang and Xu as joint inventors. [Id. ¶¶ 44–45]. Defendants further propose to add a series of factual allegations to the Counterclaim Complaint in support of the correction of inventorship claim. See [id. ¶¶ 17, 26–27, 33].

i. Good Cause

Although it is a close call, the Court concludes that Defendants have been reasonably diligent in proposing the amended counterclaim. Defendants claim that they were “poorly positioned” to determine the precise scope of their counterclaims by October 28, 2018, the time

an amended pleading would have been due, because document production had not commenced, interrogatories had not been served, and depositions had not started. [ECF No. 71 at 8]. They represent that although they received documents on January 30, 2019 and lab notebooks in February and March 2019 and took depositions in June and July 2019, it was not until they prepared for Dr. Xu's deposition that they "fully understood the nature and extent of his and Dr. Wang's inventive contributions to the '321 . . . Patent[]." [*Id.* at 8–9]. The Court credits Defendants' representations and interprets the delay in bringing the counterclaims related to the '321 Patent as result of a lengthy and slow discovery process rather than bad faith or indifference. *See Penobscot Nation v. Mills*, No. 12-cv-00254-GZS, 2014 WL 442429, at *3 (D. Me. Feb. 4, 2014) ("Defendant's request to amend does not reflect delay, rather it reflects the developing factual record related to this litigation."). Furthermore, the Court does not find that Defendants have acted in bad faith in bringing this motion to amend at this time, as their alternative to doing so was to initiate a new action, which might have invited a greater expenditure of judicial resources than the present motion practice.

While Rule 16(b)'s "good cause" standard "focuses on the diligence (or lack thereof) of the moving party more than it does on any prejudice to the party-opponent," *Somascan, Inc. v. Philips Med. Sys. Nederland, B.V.*, 714 F.3d 62, 64 (1st Cir. 2013), prejudice is still a factor to be considered. Despite Plaintiffs' protestations that the proposed amendment will prejudice them in part because "fact discovery has closed," any prejudice to Plaintiffs will be limited because the Court has already permitted an extension to fact discovery and ordered the parties to propose a new schedule. *See* [ECF No. 72; ECF No. 75-1 at 20–23]; *Gouin*, 325 F.R.D. at 523 (finding no prejudice to non-moving party where court also permitted motion to alter discovery deadlines and delay trial); *Savoy v. White*, 139 F.R.D. 265, 269 (D. Mass. 1991) (concluding

that amendment would not unduly prejudice non-moving party where new claims “closely relate to claims in the original complaint,” no trial date was set, and parties would only be “inconvenienced” by resuming a deposition). To further limit any prejudice to Plaintiffs, the Court will not tolerate delays by Defendants in producing discovery, including making Dr. Xu available for a deposition.

ii. Futility

In addition to good cause, futility presents another potential bar to amendment. “If leave to amend is sought before discovery is complete and neither party has moved for summary judgment, the accuracy of the ‘futility’ label is gauged by reference to the liberal criteria of Federal Rule of Civil Procedure 12(b)(6).” Hatch v. Dep’t for Children, Youth & Their Families, 274 F.3d 12, 19 (1st Cir. 2001). Under this standard, an amendment will not be deemed futile unless it fails to support a “plausible entitlement to relief.” Rodriguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 95 (1st Cir. 2007) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559 (2007)).

35 U.S.C. § 256 “creates a cause of action in the district courts for correction of non-joinder of an inventor on a patent provided the non-joinder error occurred without deceptive intent.” Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1358 (Fed. Cir. 2004). The Court summarized the relevant legal principles controlling a correction of inventorship claim in its memorandum and order denying Plaintiffs’ motion to dismiss the original counterclaims. See Astellas Inst. for Regenerative Med. v. Imstem Biotechnology, Inc., No. 17-cv-12239-ADB, 2018 WL 4685565, at *3 (D. Mass. Sept. 28, 2018). Now, as then, the record before the Court is simply too limited for the Court to conclude that any contributions by Drs. Wang and Xu to the ’321 Patent were not inventive concepts, and Plaintiffs have not demonstrated that any such

contributions were insignificant as a matter of law. A determination of the particular significance of any contributions of Drs. Wang or Xu to the '321 Patent requires a factual record not yet available to the Court. For these reasons, the Court concludes that the proposed amendment asserting a correction of inventorship claim is not futile.

iii. Judicial Economy

Judicial economy may also be considered when deciding motions to amend. See EMC Corp. v. Pure Storage, Inc., 310 F.R.D. 194, 202–03 (D. Mass. 2015); Rockingham Cty. Nursing Home, 2014 WL 176580, at *9–10. There can be no dispute that allowance of the correction of inventorship counterclaim promotes judicial economy. In lieu of litigating a new, related action concerning the '321 Patent, the parties may move forward with trial in April 2020 and litigate inventorship issues related to the '551, '956, and '321 Patents with only a slight extension of fact discovery. See [ECF No. 71 at 11]. Plaintiffs' arguments concerning collateral estoppel underscore the benefits of trying these claims together. See [ECF No. 75-1 at 19–20].

3. Adding Dr. Xu to Existing '956 Patent Counterclaim

Finally, Defendants propose to add Dr. Xu to the exiting correction of inventorship claim for the '956 Patent. See, e.g., [ECF No. 71-2 ¶¶ 36–41]. Defendants claim that “it was not until preparing for depositions with Dr. Xu – who lives in Macau and was difficult to communicate with before he came to the United States for his July 3, 2019 deposition – that Defendants fully understood the nature and extent of his . . . inventive contributions to the . . . '956 Patent[.]” [ECF No. 71 at 8–9]. They further state that Dr. Xu did not focus on the claims in the '956 Patent until he came to the U.S. for his deposition and met his lawyers in-person for the first time. [ECF No. 81 at 2–3].

There is no excuse for Dr. Xu's lack of diligence in asserting counterclaims related to the '956 Patent. Dr. Xu's co-defendants, ImStem and Dr. Wang, asserted a counterclaim seeking a correction of inventorship on the '956 Patent on January 10, 2018. [ECF No. 20]. Dr. Xu did not file his own answer until June 8, 2018, at which time he had been on notice of the Counterclaim Complaint for nearly six months. [ECF No. 33]. At the time of the filing of the proposed amended counterclaims, Dr. Xu had been aware of the Counterclaim Complaint for over eighteen months. This apparent indifference by Dr. Xu cannot be overcome by any geographic or language barriers that he or his counsel may face and precludes a finding of good cause. See O'Connell, 357 F.3d at 155 (describing diligence as the touchstone of the "good cause" analysis and noting that "[i]ndifference" by the moving party" may preclude leave to amend (citing Rosario-Diaz v. Gonzalez, 140 F.3d 312, 315 (1st Cir. 1998))).

III. CONCLUSION

Accordingly, Defendants' motion to amend [ECF No. 70] is GRANTED in part and DENIED in part. Defendants may amend their answer to include a statute of limitations defense and may amend the Counterclaim Complaint to include a correction of inventorship counterclaim for the '321 Patent on behalf of Drs. Wang and Xu. Defendants may not amend the Counterclaim Complaint to add Dr. Xu to the existing correction of inventorship counterclaim for the '956 Patent. The parties shall file a proposed amended schedule with the Court in which the case is trial-ready by April 2020.

SO ORDERED.

August 21, 2019

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE